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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,143

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Ronald James Jandacek

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HASSE & NESBITT LLC

8837 CHAPEL SQUARE DRIVE

SUITE C

CINCINNATI, OH 45249

EXAMINER

WALLENHORST, MAUREEN

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,143	<b>Applicant(s)</b> JANDACEK ET AL.	
	<b>Examiner</b> Maureen M. Wallenhorst	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/3/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Mattson et al (US 3,600,186).

Mattson et al teach of a low calorie fat-containing food composition comprising triglyceride dietary fat and a non-absorbable fat material in the form of a fatty acid ester compound having at least 4 fatty acid ester groups. From about 10% to about 100% of the total fat in the composition comprises a sugar or sugar alcohol fatty acid ester having at least 4 fatty acid ester groups, each of the fatty acids having from about 8 to about 22 carbon atoms. The sugar or sugar alcohol fatty acid esters are less digested or absorbed than normal triglyceride fat in the intestinal tract. Examples of the sugar in the sugar fatty acid ester include glucose and sucrose. The four hydroxyl groups of the sugar compound are esterified with a fatty acid having from about 8 to about 22 carbon atoms. When 22 carbon atoms are present in the fatty acid and

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the sugar is sucrose, the compound is sucrose behenate. Therefore, the test composition can contain a dietary fat and a marker consisting of a predetermined amount of sucrose polyester comprising sucrose behenate. The test composition can also comprise protein (i.e. casein) and carbohydrates (i.e. flour). The test composition can contain 10%, 25% or 100% of the non-absorbable fat compound with the remainder of the fat portion of the composition being dietary triolein. See lines 9-72 in column 2 and columns 5-6 in Mattson et al. Mattson et al also teach that the test composition including the dietary fat and the non-absorbable sugar fatty acid ester material can be used in a fat balance experiment that measures the total dietary fat absorption by the digestive tract of a subject. In the experiment, a subject such as a rat is fed a test meal comprising the test composition (i.e. a combination of dietary fat and the non-absorbable sugar fatty acid ester material such as sucrose polyester), and a sample of fecal matter is collected from the subject at a time point after the test meal has been ingested. The amount of fat eaten and the amount of fat in the feces are determined. The difference between these two values is the amount of fat absorbed by the digestive tract of the subject. Mattson et al teach that the portion absorbed of the amount fed expressed as a percentage is the coefficient of absorbability and is an indication of the relative available calories of the test composition. See lines 32-43 in column 4 of Mattson et al.

4. Claims 1-2 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (US 5,085,884).

Young et al teach of a reduced caloric food composition comprising a digestible triglyceride fat or oil and a nondigestible fat component. The nondigestible component comprises nondigestible solid or liquid polyol fatty acid polyesters having ester groups

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comprising combinations of unsaturated (C12 or higher) and/or short chain (C2-C12) saturated fatty acid radicals and long chain (C20 or higher) saturated fatty acid radicals. The nondigestable fat component is a liquid or solid sugar fatty acid polyester, wherein the sugar can be sucrose. The sugar fatty acid polyester contains at least 4 fatty acid ester groups which are nondigestable and consequently non-absorbable by the human body. The sugar starting material of these polyesters are esterified with fatty acids containing from 2 to 24 carbon atoms, preferably 8 to 22 carbon atoms. Examples of the fatty acids include behenic acid, thus making the non-absorbable compound a sugar (i.e. sucrose) behenate. Young et al teach of the manufacture of sucrose C12-C22 polyesters such as sucrose behenate in the examples. See the abstract, lines 20-50 in column 4, lines 15-59 in column 7, lines 1-11 in column 8 and columns 13-14 in Young et al.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5-8 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mattson et al. For a teaching of Mattson et al, see previous paragraphs in this Office action.

Mattson et al fail to teach that that the fat balance experiment can be used to diagnose malabsorption of dietary fat by the digestive tract of a subject and impairment of dietary fat digestion. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the fat balance experiment taught by Mattson et al for diagnosing malabsorption of dietary fat by the digestive tract of a subject and impairment of dietary fat digestion since that fat balance experiment disclosed by Mattson et al serves to determine the digestive absorption of a test composition containing both a dietary fat and a non-absorbable sucrose polyester marker, and thus, any absorption results deviating from the normal, expected results would inherently and obviously serve as an indication or diagnosis of malabsorption by the digestive tract of the subject fed the test composition.

8. Claims 4, 9, 12 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mattson et al in view of Janghorbani et al (US 6,006,754, submitted in the Information Disclosure Statement filed on July 17, 2006). For a teaching of Mattson et al, see previous paragraphs in this Office action. Mattson et al fail to teach that test composition fed to the subject in the method for determining the dietary fat absorption by the digestive tract of the subject contains a colorant material.

Janghorbani et al teach of a method and composition for measuring fat absorption. The method comprises the steps of feeding a person a composition comprising a labeled dietary fat, a non-absorbable marker and a means for coloring stool, allowing the composition to travel through the digestive tract of the person, monitoring the stool from the person for the appearance

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of the coloring means, collecting stool containing the coloring means, and measuring the amount of the non-absorbable marker and labeled dietary fat in the colored stool to determine the portion of fat digested and/or absorbed by the person. The dietary fat includes a triglyceride, the non-absorbable marker includes a non-absorbable salt containing an element from the lanthanide group, and the coloring means includes a dye such as carmine red. See lines 1-26 and 53-67 in column 3, lines 1-32 in column 4 and lines 24-27 in column 7 of Janghorbani et al. Stool samples from the person are collected for five days after administration of the composition.

Based upon the combination of Mattson et al and Janghorbani et al, it would have been obvious to one of ordinary skill in the art to include a colorant material such as a dye in the test composition taught by Mattson et al used for determining the dietary fat absorption by the digestive tract of a subject in order to provide an easy means to identify the portion of the subject's stool to collect and analyze for fat content after the test composition has been ingested, in accordance with the teaching of Janghorbani et al.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Jandacek et al (US 5,017,398) who teaches of a bread spread composition containing both dietary fat and a non-digestible sucrose polyester.

10. Applicant's arguments filed November 3, 2008 have been fully considered but they are not persuasive.

The previous objection to the abstract made in the last Office action mailed on July 3, 2008 has been withdrawn in view of Applicants' amendments to the abstract. The previous

rejections of the claims under 35 USC 112, first and second paragraphs have also been withdrawn in view of the amendments made to the claims.

Applicants argue the rejection of the claims under 35 USC 102 as being anticipated by Mattson et al by stating that the compound sucrose behenate is not specifically named or disclosed expressly or inherently in Mattson et al, and the experiments described by Mattson et al only relate to oleic fatty acid esters and not behenic esters. In response to this argument, it is noted that sucrose behenate is inherently disclosed by the teaching of Mattson et al since the non-absorbable fat material in the composition is described as a sugar alcohol fatty acid ester compound having at least 4 fatty acid ester groups, wherein the sugar can be sucrose and the fatty acid chains of the fatty acid ester groups can contain between 8 and 22 carbon atoms. Sucrose behenate is encompassed by the teaching of Mattson et al since sucrose behenate is a sugar fatty acid ester compound having sucrose and at least 4 fatty acid ester groups with 22 carbon atoms each. Also, lines 1-4 in column 3 of Mattson et al teach that the fatty acids in the compound can be "behenic". The experiments described by Mattson et al are only one specific example of the sugar alcohol fatty acid ester compounds encompassed by the overall teaching of the reference, and all disclosure and reasonable interpretation of a prior art reference must be evaluated, including non-preferred embodiments. See *In re Fracalossi*, 215 USPQ 569 (CCPA 1982).

Applicants also argue that the fat balance experiment taught by Mattson et al does not distinguish between the fatty acids contributed by triolein and the fatty acid ester test materials since Mattson et al do not separately measure the amount of dietary fat and the amount of sucrose polyester recovered in the fecal sample. However, contrary to Applicants' argument, it is



noted that Mattson et al do separately measure the absorbability of the dietary fat (triolein) and the test materials containing a sucrose alcohol fatty acid ester compound by using the formula depicted on lines 1-3 of column 6. This formula is used to determine the absorbability of each of the test materials at each level of total dietary fat. See lines 71-75 in column 5 and lines 1-19 in column 6 of Mattson et al.

Applicants argue the rejection of the claims under 35 USC 102(b) as being anticipated by Young et al by stating that there is no express description or teaching of the amounts of digestible fat and non-digestible fat marker in the food compositions as being in "pre-determined amounts", as required by Applicants' claims. In response to this argument, it is noted that Young et al teach of specific, pre-determined amounts of the non-digestible fat component and the digestible triglyceride fat or oil in lines 18-30 of column 17 where it is taught that the composition can contain between 0 and 90% of a digestible triglyceride oil or fat, and more preferably between 0 and 25% of a digestible triglyceride oil or fat, with the remainder of the composition comprising the nondigestible fat component that comprises a sugar fatty acid polyester compound. Therefore, contrary to Applicants' arguments, the composition taught by Young et al does contain specific, pre-determined amounts of the digestible fat and the non-digestible fat marker.

Applicants also argue that neither Young et al nor Mattson et al teach of a method for diagnosing malabsorption of dietary fat by the digestive tract of a subject, and impairment of dietary fat digestion in a subject. In response to this argument, it is noted that in view of the teaching of Mattson et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the fat balance experiment taught by Mattson et al for

diagnosing malabsorption of dietary fat by the digestive tract of a subject and impairment of dietary fat digestion since that fat balance experiment disclosed by Mattson et al serves to determine the digestive absorption of a test composition containing both a dietary fat and a non-absorbable sucrose polyester marker, and thus, any absorption results deviating from the normal, expected results would inherently and obviously serve as an indication or diagnosis of malabsorption by the digestive tract of the subject fed the test composition.

Applicants also argue that neither Mattson et al nor Young et al disclose or make obvious a method where the amount of dietary fat and the amount of sucrose polyester in a fecal sample are each measured. However, the fat balance experiment taught by Mattson et al does measure the amount of dietary fat and the amount of a sugar alcohol fatty acid ester compound, which can be a sucrose polyester, in a fecal sample using the equation recited on lines 1-3 of column 6 in Mattson et al.

Applicants fail to present any different arguments concerning the reference to Janghorbani et al other than the ones already discussed above, and therefore, no further comment concerning Janghorbani et al will be made.

For all of the above reasons, Applicants' arguments are not found persuasive.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1797

mmw

January 5, 2009

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797